Study to Provide Continued Access to Treatment for Patients Completing a Previous Trial With Efanesoctocog Alfa

NCT06716814

Status	RECRUITING
Phase	Phase 3
Sponsor	Swedish Orphan Biovitrum
Enrollment	104 participants

Key Eligibility Criteria

Inclusion (3)

- Capable of giving signed informed consent. Parents or legally designated representatives' consent is required for patients who are below 18 years of age or unable to give consent. Patients who are below 18 years of age may provide assent in addition to the parents'/legally designated representatives' consent, if appropriate.
- Must have completed one of the required parent studies: Sobi.BIVV001-001, Sobi.BIVV001-003, or LTS16294, and be receiving a clinical benefit from the efanesoctocog alfa treatment, as judged by the Investigator.
- Willingness and ability of patient or their parent or legally designated representative to complete training in the use of the study patient diary and to complete the diary throughout the study.

Exclusion (3)

- Positive inhibitor result (assessed by central laboratory), defined as e0.6 Bethesda units (BU)/mL, at Baseline Visit.
- Ongoing or planned participation in any interventional clinical study at Baseline Visit.
- Patient not suitable for participation, whatever the reason, as judged by the Investigator, including medical or clinical conditions, or patients potentially at risk of noncompliance to study procedures.

Locations (22 total)

Sobi Investigational Site, Plovdiv, Bulgaria
Sobi Investigational Site, Sofia, Bulgaria
Sobi Investigational Site, Bordeaux, France
... and 19 more locations